UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION II

DATE: MAY 13 2010

SUBJECT: Leak Detection and Repair (LDAR) Inspection of Pfizer Pharmaceuticals in Barceloneta, PR

FROM: John Kushwara, Chief
Monitoring and Assessment Branch (2DESA-MAB)

TO: Ken Eng, Chief
Air Compliance Branch (2DECA-ACB)

On March 4-5, 2010, Reshma Punwasie and Erwin Smieszek of my staff conducted an LDAR inspection at Pfizer Pharmaceuticals, located in Barceloneta, PR, to determine compliance with 40 CFR 63 Subpart H. Attached is the inspection report.

If you have any questions, please feel free to call Reshma Punwasie at 732-321-6682.

Attachments

cc: Karl Mangels, 2DECA-ACB
Francisco Claudio, 2CEPD-MPCB
Teresita Rodriguez, 2CEPD-MPCB

Leak Detection and Repair Inspection Report

Pfizer Pharmaceuticals LLC
Road 2, Km. 58.2
Barceloneta, PR 00617

40 CFR Part 63, Subpart H
AIRS ID: 72-017-00010

Inspection Dates: March 4 -5, 2010

Participating Personnel:

US Environmental Protection Agency
Reshma Punwasie, Region 2 – DESA/MAB
Erwin Smieszek, Region 2 – DESA/MAB
Francisco Claudio, Region 2 - CEPD/MPCB

Report Prepared by:

5/12/10
Reshma Punwasie, Environmental Scientist

Approved for the Director by:

John S. Kushwara 5/13/10
John S. Kushwara, Chief
Monitoring & Assessment Branch

LDAR Inspection of Pfizer Pharmaceuticals in Barceloneta, PR

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Inspection Date:

March 4-5, 2010

Inspection Attendees:

Reshma Punwasie, EPA-DESA; Erwin Smieszek, EPA-DESA; Francisco Claudio, EPA-CEPD; Gerardo Santiago, PR-EQB (Puerto Rico Environmental Quality Board); Ramon Marrero, Pfizer; Eduardo Cordero, Pfizer; Jesus Santos, Pfizer; Evelyn Soto Vazquez, Pfizer; Hector Arroyo, Pfizer.

Attendance sheets can be found in Appendix A of this report.

Introduction:

Pfizer Pharmaceuticals (BMS), located in Barceloneta, PR, is subject to the leak detection and repair program (LDAR) requirements of 40 CFR 63 Subpart H (HON). Pfizer produces the active pharmaceutical ingredients (API) used to produce Cardura, Procardia, Zoloft, and Glucophage. All processes are batch process operations. Pfizer is subject to HON due to the use of methylene chloride in several of its manufacturing batch processes.

Valves are monitored quarterly, pumps and agitators are monitored monthly, and connectors are monitored annually. Visual monitoring is also conducted on pumps and agitators weekly. The leak definitions are as follows: valves and connectors are considered leaking at ≥500 ppm; pumps at ≥1000 ppm; and agitators at ≥10,000 ppm. Table 1 below summarizes Pfizer's monitoring frequency and leak definitions.

Component Type	Leak Definition	Monitoring Frequency	Visual Inspection Frequency
Valves	500 ppm	Quarterly	N/A
Connectors	500 ppm	Annually	N/A
Pumps	1,000 ppm	Monthly	Weekly
Agitators	10,000 ppm	Monthly	Weekly

Table 1 – Pfizer's Monitoring Frequency

Management System Review:

Pfizer Pharmaceuticals performs all LDAR monitoring in-house. One Pfizer employee, Hector Arroyo, is responsible for LDAR monitoring, and can monitor approximately 200

components in one 8-hour day of work. It takes approximately 2 weeks to complete valve monitoring at Pfizer.

If a leak is detected during routine monitoring, a yellow leak tag is attached to the leaking component, and a first attempt at repair is performed by Hector Arroyo. After the repair attempt re-monitoring is performed. If the first attempt was not successful, Hector completes a work order in PGEMS (Pfizer Global Engineering Maintenance System), which is sent to the maintenance department. Maintenance will attempt a repair on the component and contact Hector for re-monitoring. First attempts are conducted within 5 days and final repairs are completed within 15 days. If a repair is expected to take more than 15 days, the component is taken out of service to avoid placing it on a Delay of Repair (DOR) list.

Leak records, work orders, and leak repairs for 2005 through 2009 were reviewed by EPA and EQB, and found to be satisfactory. Pfizer currently records all monitoring data manually, and has been recording data this way for approximately 1 year, since purchasing Toxic Vapor Analyzers for monitoring. Prior to this Pfizer recorded and stored monitoring data electronically using an LDAR database called Fugitive. Fugitive has since gone out of business and Pfizer is having difficulty retrieving historic LDAR monitoring data. Region 2 requested a copy of raw data from the Fugitive program, but Pfizer, along with IT help was not able to provide a searchable copy of raw data.

Technical System Audit:

Pfizer owns and maintains 3 Toxic Vapor Analyzers (TVA), which are used for all LDAR monitoring. Reshma Punwasie observed routine instrument calibration by Hector Arroyo, and found Pfizer was performing a "bump check" or a calibration drift test in place of a daily calibration. As per §63.180(b)(3), the instrument shall be calibrated before use on each day of its use by the procedures specified in Method 21 of 40 CFR Part 60, Appendix A. According to Hector Arroyo (with translation by Jesus Santos), calibrations are only performed when the instrument response shows readings that have drifted more than 10% of the actual calibration gas concentrations. A "bump check" is performed each day the instrument is used for monitoring, and is recorded on an LDAR Program TVA-1000B Calibration Log. Since Pfizer cites it as a calibration, there was no way to determine that it was not a legitimate calibration until the operation was observed by EPA.

The calibration gases used by Pfizer are zero air, 550 ppm CH4, 1,000 ppm CH4, and 9,500 ppm CH4. These gases are certified to be within ±2 % accuracy by the manufacturer, and meet all the requirements of Method 21. Calibration precision tests are performed every quarter, as required by Method 21. Response time tests have never been performed by Pfizer, but are required before placing an instrument into service, and if a modification is made to the sample pumping system or flow configuration by section 8.1.3 of Method 21. Pfizer started performing response time testing on March 5, 2010 after Region 2 inspectors explained that it was required by Method 21.

Compliance Monitoring:

Region 2 performed side by side LDAR monitoring with Pfizer's LDAR technician in order to audit his technique relative to Method 21, and instrument performance. A total of 341 points were monitored during this inspection, with 4 exceedances detected and 2 visual leaks found. These results can be found in Table 2 of this report.

Region 2 inspectors also found 3 open-ended lines during compliance monitoring. As per 40 CFR 63.167(a), each open-ended valve or line shall be equipped with a cap, blind flange, plug, or a second valve. Pictures of the open-ended lines (OELs) found during monitoring can be found in Appendix B

Follow-Up:

Reshma Punwasie, of EPA Region 2, received a letter from Eduardo Cordero, of Pfizer, dated March 17, 2010 regarding findings brought up during the EPA inspection. The letter documents successful repairs to the 4 exceedances and 2 visual leaks detected by EPA. Included in the letter were pictures of plugs added to 2 of the 3 OELs found by EPA. Pfizer included a third picture for a cap added to component TS-HV-111B04. This component was not found to be leaking or missing a cap by EPA. Pfizer failed to show that a cap was added to the OEL found by EPA at component G-HV-07S84-002. Pfizer also explained that they are now in compliance with the requirements of Method 21 for calibration and response time testing. The letter from Pfizer can be seen in Appendix C

Summary of Findings:

- Pfizer does not perform calibrations each day its monitoring instrument is being used for LDAR monitoring.

  40 CFR 63.180(b)(3) - *The instrument shall be calibrated before use on each day of its use by the procedures specified in Method 21 of 40 CFR part 60, appendix A.*

- Pfizer has never performed response time testing on any of its monitoring instruments.

  Method 21 section 8.1.3 of 40 CFR part 60, appendix A - *Response Time. The response time test is required before placing the instrument into service. If a modification to the sample pumping system or flow configuration is made that would change the response time, a new test is required before further use.*

- Region 2 inspectors found 3 Open-Ended Lines (OELs) at Pfizer.

  40 CFR 63.167(a) - *Standards: Open-ended valves or lines. (a)(1) Each open-ended valve or line shall be equipped with a cap, blind flange, plug, or a second*

valve, except as provided in §63.162(b) of this subpart and paragraphs (d) and (e) of this section.

(2) The cap, blind flange, plug, or second valve shall seal the open end at all times except during operations requiring process fluid flow through the open-ended valve or line, or during maintenance or repair.

Table 2 - LDAR Monitoring Data

Facility Name:	Pfizer Pharmaceuticals
Facility Location:	Barceloneta, PR
Monitoring Dates:	3/4/10 - 3/5/10
EPA Monitoring Conducted by:	Reshma Punwasie and Erwin Smieszek
EPA Instrument and Serial number:	TVA 1000B S/N 0610416691
Facility Monitoring Conducted by:	Hector Arroyo
Facility Instrument and Serial number:	TVA 1000B S/N 0723424505

Background Monitoring Results

Date			EPA Reading (ppm)	Facility Reading (ppm)	Notes
3/4/10			0.47	2.12	
3/5/10			1.0	3.0	

Side by Side Leak Monitoring Results

Date	Component ID	Component Type	EPA Reading (ppm)	Facility Reading (ppm)	Notes
		Key: V - VALVE P - PUMP	F- FLANGE · OPEN-ENDED LINE		
3/4/10	S-P-01S102-000	P	1	3	Area S - Storage
3/4/10	S-P-01S102-001	F	1	2.9	
3/4/10	S-P-01S102-002	F	1	3.5	
3/4/10	S-HV-07S102-000	V	1	2.9	
3/4/10	-001	F	1	7.5	
3/4/10	-002	F	1	5	
3/4/10	S-HV-10S102-000	V	1	2.5	
3/4/10	-001	F	1	2.6	
3/4/10	-002	F	1	2.8	
3/4/10	S-HV-11S102-000	V	1	2.5	
3/4/10	-001	F	1	4.4	
3/4/10	-002	F	1	2.5	
3/4/10	S-HV-08S102-000	V	1	2.8	
3/4/10	-001	F	1	2.7	
3/4/10	-002	F	52	27	
3/4/10	S-HV-09S102-000	V	1	2.6	
3/4/10	001	F	1	2.4	
3/4/10	002	F	1	2.6	
3/4/10	S-HV-05S102-000	V	1	3.1	
3/4/10	-001	F	1	3	
3/4/10	-002	F	1	2.8	
3/4/10	S-HV-06S102-000	V	1	3.1	
3/4/10	-001	F	1	3.1	
3/4/10	-002	F	1	3	
3/4/10	S-FL-014S102-000	F	1	3.1	
3/4/10	S-P-01S100-000	P	1		
3/4/10	-001	F	1		
3/4/10	-002	F	1		
3/4/10	S-HV-09S100-000	V	1		
3/4/10	-001	F	1		
3/4/10	-002	F	1		
3/4/10	S-HV-08S100-000	V	1		
3/4/10	-001	F	1		
3/4/10	-002	F	1		
3/4/10	S-HV-06S100-00	V	1		

Date	Component ID	Component Type	EPA Reading (ppm)	Facility Reading (ppm)	Notes
3/4/10	-001	F	1		
3/4/10	-002	F	1		
3/4/10	S-FL-014S100-000	F	1		
3/4/10	S-HV-05S100-000	V	1		
3/4/10	-001	F	1		
3/4/10	-002	F	1		
3/4/10	S-HV-07S100-000	V	1		
3/4/10	-001	F	1		
3/4/10	-002	F	1		
3/4/10	S-HV-10S100-000	V	1		
3/4/10	-001	F	1		
3/4/10	-002	F	1		
3/4/10	S-HV-11S100-000	V	1		
3/4/10	-000	F	1		
3/4/10	-000	F	1		
3/4/10	S-P-01S98-000	P	4		
3/4/10	-001	F	2		
3/4/10	-002	F	1		
3/4/10	S-FL-014S98-000	F	30		
3/4/10	S-HV-006S98-000	V	1		
3/4/10	-001	F	1		
3/4/10	-002	F	8		
3/4/10	S-HV-005S98-000	V	1		
3/4/10	-001	F	1		
3/4/10	-002	F	1		
3/4/10	S-HV-09S98-000	V	12		
3/4/10	-001	F	1		
3/4/10	-002	F	1		
3/4/10	S-HV-08S98-000	V	1		
3/4/10	-001	F	1		
3/4/10	-002	F	1		
3/4/10	S-HV-07S98-000	V	3		
3/4/10	-001	F	3		
3/4/10	-002	F	32		
3/4/10	S-HV-10S98-000	V	2		
3/4/10	-001	F	2		
3/4/10	-002	F	2		
3/4/10	S-HV-13S98-000	V	1		
3/4/10	-001	F	1		
3/4/10	-002	F	1		
3/4/10	S-HV-11S98-000	V	1		
3/4/10	-001	F	40		
3/4/10	-002	F	9		
3/4/10	S-P-01S97-000	P	3		
3/4/10	-001	F	1		
3/4/10	-002	F	1		
3/4/10	S-FL-014S97-000	F	1		
3/4/10	S-HV-05S97-000	V	1		
3/4/10	-001	F	1		
3/4/10	-002	F	1		
3/4/10	S-HV-NT-000	V	1		
3/4/10	-001	F	1		
3/4/10	-002	F	1		
3/4/10	S-HV-17S97-000	V	1		
3/4/10	-001	F	1		
3/4/10	-002	F	1		
3/4/10	S-HV-NT-000	V	1		
3/4/10	-001	F	1		
3/4/10	-002	F	1		
3/4/10	S-HV-07S97-000	V	1		
3/4/10	-001	F	7		
3/4/10	-002	F	1		
3/4/10	S-HV-10S97-000	V	1		
3/4/10	-001	F	1		
3/4/10	-002	F	1		
3/4/10	S-HV-NT-000	V	1		
3/4/10	-001	F	1		
3/4/10	-002	F	1		
3/4/10	S-FL-017S97-000	F	1		
3/4/10	S-HV-14S97-000	V	1		

Date	Component ID	Component Type	EPA Reading (ppm)	Facility Reading (ppm)	Notes
3/4/10	-001	F	1		
3/4/10	-002	F	1		OPEN ENDED LINE (OEL)
3/4/10	NT FILTER 000	F	1		
3/4/10	NT VALVE 000	V	1		
3/4/10	ABOVE FILTER 001	F	1		
3/4/10	002	F	1		
3/4/10	S-HV-16S97-000	V	1		
3/4/10	001	F	1		
3/4/10	002	F	1		
3/4/10	S-HV-11S97-000	V	1		
3/4/10	001	F	1		
3/4/10	002	F	1		
3/4/10	S-96 NT-000	PLUG	1		
3/4/10	001	F	1		
3/4/10	002	F	1		
3/4/10	S-HV-05S96-000	V	1		
3/4/10	001	F	1		
3/4/10	002	F	1		
3/4/10	S-HV-06S96-000	V	1		
3/4/10	001	F	1		
3/4/10	002	F	1		
3/4/10	NT 014-000	F	1		
3/4/10	NT-000	V	1		
3/4/10	001	F	1		
3/4/10	002	F	1		
3/4/10	S-HV-08S96-000	V	1		
3/4/10	001	F	1		
3/4/10	002	F	300	125	
3/4/10	S-HV-07S96-000	V	1		
3/4/10	001	F	1		
3/4/10	002	F	1		
3/4/10	NT-000	V	1		
3/4/10	001	F	1		
3/4/10	002	F	1		
3/4/10	S-HV-11S96-000	V	1		
3/4/10	001	F	1		
3/4/10	002	F	1		
3/5/10	TS-HV-111B04-000	V	1		TS 104
3/5/10	001	F	1600	1000	
3/5/10	002	F	28		
3/5/10	NT-000	PLUG	935	510	
3/5/10	NT-TS-HV-111B04-00	V	3		
3/5/10	001	F	3		
3/5/10	002	F	2		
3/5/10	TS-HV-37BO4-000	V	3		
3/5/10	001	F	2		
3/5/10	002	F	1		
3/5/10	NT-000	F	1		
3/5/10	NT-000	V	1		
3/5/10	NT-002	F	1		
3/5/10	NT-000	F	14		
3/5/10	NT-000	V	1		
3/5/10	NT-002	F	1		
3/5/10	NT-000	F	1		
3/5/10	NT-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	5		
3/5/10	NT-000	F	1		
3/5/10	NT-000	V	1		
3/5/10	NT-000	PLUG	1		
3/5/10	TS-HV-100AB04-000	V	69		
3/5/10	001	F	9		
3/5/10	002	F	360		
3/5/10	003	PLUG	1120	600	
3/5/10	NT-000	V	4		
3/5/10	001	F	6		
3/5/10	002	F	21		
3/5/10	NT-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		

Date	Component ID	Component Type	EPA Reading (ppm)	Facility Reading (ppm)	Notes
3/5/10	NT-000	PLUG	1		
3/5/10	NT-000	PLUG	12		
3/5/10	TS-HV-98B04-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	NT-000	V	15		
3/5/10	001	F	396	371	
3/5/10	002	F	1		
3/5/10	NT-000	PLUG	5		
3/5/10	NT-000	PLUG	120	105	
3/5/10	TS-HV-99B04-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	000	PLUG	1		
3/5/10	TS-HV-101B04-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	000	PLUG	44		
3/5/10	TS-HV-146B08-000	V	2		TS 108
3/5/10	001	F	1		
3/5/10	002	F	2		
3/5/10	TS-HV-145B08-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	G-HV-06S59-000	V	1		AREA G
3/5/10	001	F	3		
3/5/10	002	F	32		
3/5/10	G-P-002S59B-000	P	2		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	G-FL-013S59-001	F	1		
3/5/10	002	V	1		
3/5/10	003	F	1		
3/5/10	G-HV-05S59-000	V	1		
3/5/10	002	PLUG	1		
3/5/10	G-HV-07S59-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	G-FL-012S59-000	F	1		
3/5/10	G-HV-08S59-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	G-HV-09S59-000	V	1		
3/5/10	002	PLUG	1		
3/5/10	G-HV-03S59-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	G-HV-04S59-000	V	1		
3/5/10	G-HV-11S59-000	V	1		
3/5/10	001	F	1		
3/5/10	002	PLUG	1		
3/5/10	G-XV-02S59-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	003	F	2		
3/5/10	G-HV-03S74-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	G-HV-04S74-000	V	1		
3/5/10	001	F	1		
3/5/10	002	PLUG	1		
3/5/10	G-XV-02S74-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	003	F	1		
3/5/10	G-HV-03S76-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	G-FL-012S76-000	V	1		
3/5/10	001	F	1		

Date	Component ID	Component Type	EPA Reading (ppm)	Facility Reading (ppm)	Notes
3/5/10	002	F	1		
3/5/10	003	PLUG	1		OEL
3/5/10	G-XV-02S76-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	003	F	1		
3/5/10	G-HV-03S84-000	V	1		AREA W - HAZ WASTE
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	G-HV-04S84-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	003	PLUG	1		
3/5/10	G-XV-02S84-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	G-FL-012S84-000	F	1		
3/5/10	G-HV-035S5-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	G-HV-04S85-000	V	1		
3/5/10	001	F	1		
3/5/10	002	PLUG	1		
3/5/10	G-XV-02S85-000	V	1		
3/5/10	001	F	1		VISUAL LEAK
3/5/10	002	F	1		
3/5/10	G-FL-011S85-000	F	1		
3/5/10	G-FL-012S85-000	F	1		
3/5/10	G-HV-003S86-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	G-XV-02S86-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	G-HV-04S86-000	V	49		VISUAL LEAK
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	003	F	1		
3/5/10	004	PLUG	1		
3/5/10	G-FL-012S86-000	F	1		
3/5/10	G-P-01S84-000	P	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	G-FL-013S84-000	F	1		
3/5/10	G-HV-05S84-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	G-HV-05S85-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	G-FL-013S85-000	F	1		
3/5/10	G-FL-013S86-000	F	1		
3/5/10	G-HV-05S86-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	G-HV-15S84-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	G-FL-019S84-000	F	1		
3/5/10	G-HV-07S84-000	V	1		
3/5/10	001	F	1		
3/5/10	002	PLUG	1		OEL
3/5/10	G-HV-08S84-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	003	F	1		
3/5/10	G-HV-09S84-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	G-HV-13S84-000	V	1		

Date	Component ID	Component Type	EPA Reading (ppm)	Facility Reading (ppm)	Notes
3/5/10	001	F	1		
3/5/10	002	F	8		
3/5/10	G-HV-10S84-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	SR-P-01C01-000	P	9		AREA SR
3/5/10	001	F	8		
3/5/10	002	F	**4880**	**7112**	
3/5/10	SR-HV-43C01-000	V	4		
3/5/10	001	F	2		
3/5/10	002	F	9		
3/5/10	SR-HV-37C01-000	V	26		
3/5/10	NT-000	V	78		
3/5/10	SR-HV-36C01-000	V	9		
3/5/10	SR-FL-066C01-000	F	1		
3/5/10	SR-XV-11C01-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	SR-FL-087C01-000	F	3		
3/5/10	SR-FL-085C01-000	F	1		
3/5/10	001	F	1		
3/5/10	002	F	1		
3/5/10	SR-FL-091C01-001	F	1		
3/5/10	002	F	2		
3/5/10	SR-XV-10C01-000	V	1		
3/5/10	001	F	1		
3/5/10	002	F	54		

Total points monitored:	341
Number of OELs:	3
Number of Visual Leaks:	2
Number of leaks:	4

Appendix A:

Inspection Attendance Sheets

Pfizer Barceloneta
EPA LDAR Inspection
3/4/10

Name	Company / Agency	Position	Phone #	Email address
1) Reshma Punwasie	USEPA - R2	Env. Scientist	732-321-6682	punwasie.reshma@epa.gov
2. ERWIN SMIESZEK	USEPA - Region 2 Edison, New Jersey	ENV. ENGINEER	732-321-6719	SMIESZEK.ERWIN@EPA.GOV
3- Gerardo Santiago	EQB - Puerto Rico	Engineer	787-767-8181, x-3289	gerardo.santiago@jca.gobierno.pr
4- Jesús SANTOS	PFIZER BARCELONETA	ENGINEER AIR COMPLIANCE	787 774-7492	jesus.santos@pfizer.com
5- Francisco Claudio	USEPA	Env. Eng	787-977-5841	claudio.francisco@EPA.gov
6- Ramon Marrero	Pfizer	Env TL	787-238-9297	ramon.marrero@Pfizer.com
7- Héctor I. Arroyo	Pfizer	Tecnico Fugitive		hector.Arroyo@PFIZER.COM.

Pfizer Barceloneta

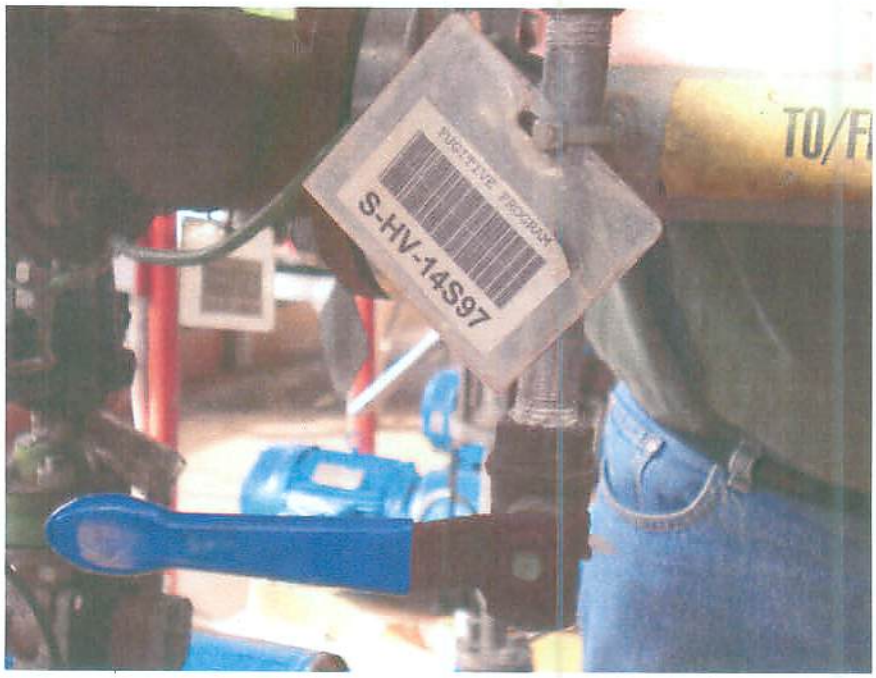
EPA LDAR Inspection

Closing Conference - 3/5/10

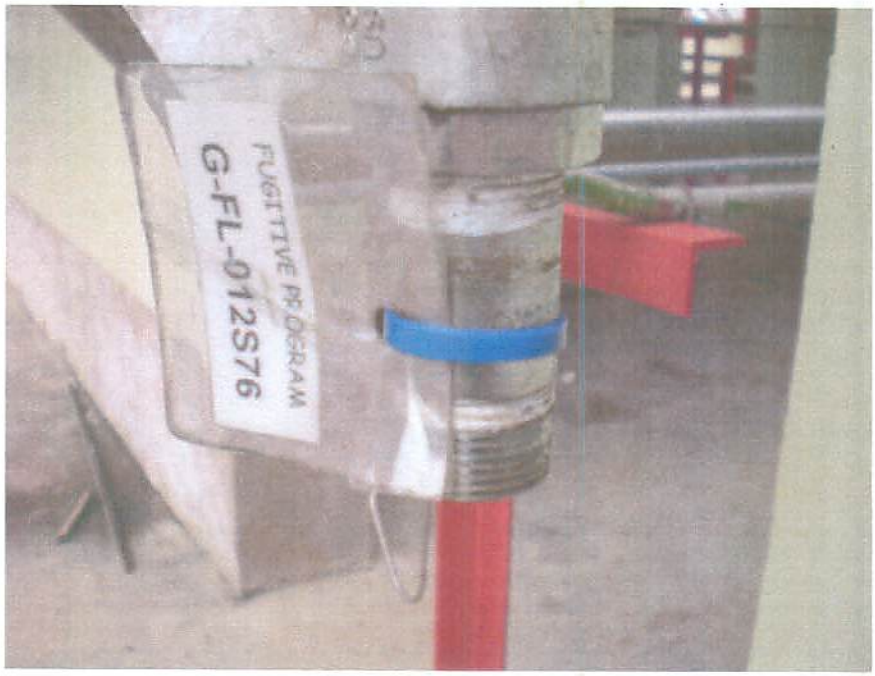
Name	Company / Agency	Position	Phone #	Email Address
1) Reshma Punwasie	USEPA R2 - Edison, NJ	Env. Scientist	732-321-6682	punwasie.reshma@epa.gov
2) Gerardo Santiago	EQB, Puerto Rico	Engineer	787-767-8181 X-3289	gerardosantiago@jca.gobierno.pr
3. Francisco Claudio	USEPA	Enforcement Officer	787-977-5841	Claudio.francisco@epa.gov
4) ERWIN SMIESZEK	USEPA.	ENV. ENGINEER	732-321 6718	SMIESZEK.ERWIN@EPA.GOV
5. Ramon Marrero	Pfizer	ENVTL	787-238-8997	ramon.marrero@pfizer.com
6. Eduardo Cordero	Pfizer	Director/TL EHS	787-654-2277	eduardo.cordero@pfizer.com
7. Jesus Santos	Pfizer		787 774-7192	jesus.santos@pfizer.com
8. Evelyn Soto Vaiquer	Pfizer	ERT Tech.	787-846-4300 Ext. 22999	evelyn.soto@pfizer.com
9- Héctor I. Arroyo	Pfizer	EHS.		hector.Arroyo@Pfizer.com.

Appendix B:

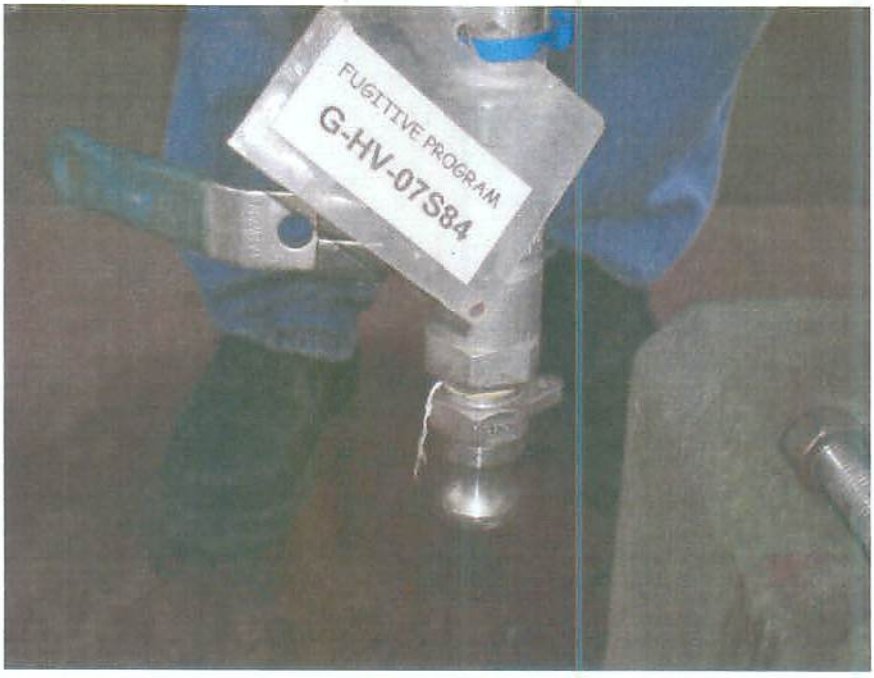
EPA Inspection Pictures



Picture 1: OEL at S-HV-14S97



Picture 2: OEL at G-FL-012S76-003



Picture 3: OEL at SR-P-01C01-002

Appendix C:

Inspection Follow-Up Letter from Pfizer

Pfizer Pharmaceuticals LLC
Barceloneta Site
Rd.2, KM.58.2, P.O.Box 628
Barceloneta, PR 00617
Tel. (787) 846-4300

Pfizer Global Manufacturing

March 17, 2010

VIA CERTIFIED MAIL, RETURN RECIPRT REQUESTED

Ms. Reshma Punwasie
Environmental Protection Agency
Raritan Depot
2890 Woodbridge Ave
Edison, NJ 08837-3679

Re: HON Leak Detection and Repair Program Inspection
Pfizer Pharmaceuticals LLC, Barceloneta

Dear Ms. Punwasie:

As agreed during the closing meeting of the March 4 and 5, 2010 USEPA inspection performed in connection with our Leak Detection and Repair (LDAR) program at our facility located in Barceloneta, Puerto Rico, we are herein submitting documentation regarding certain observations made during said inspection. For your convenience, we have identified each observation along with a Pfizer's response as follows:

1. Pfizer should evaluate and properly document its flame ionization detector (FID) instrument calibration and the response time determination on the monitoring instruments in accordance with EPA Standard Method (SM) 21.

   Pfizer Response: As you know, Pfizer responded immediately to these observations. The FID is being properly calibrated and verified as required by SM 21. Also the calibration precision test form was modified to include the response time determination. For example, the response time determined for the FID instrument was 3 seconds, which is well below the response time limit of less than 30 seconds specified in SM 21. See modified forms in Attachment I.

2. The regulations require that when a valve is found leaking, a "leaking" tag be placed and left until the valve is repaired, monitor, and re-monitor (re-monitoring to be completed within three months after the leak has been repaired).

Pfizer Response: Pfizer has implemented a practice to re-monitor the valves within two weeks after the leak has been repaired and monitored. Attachment II includes the repair work for a valve identified as leaking during the inspection. As an enhancement to our LDAR program, Pfizer is preparing a LDAR guideline (or SOP) that comprehensively addresses these requirements.

3. Three open ended lines were identified as being without a cap or a second valve.

   Pfizer Response: As you know, these open-ended lines were capped immediately during the inspection. The photographs in Attachment III document this activity.

Also, during the inspection two (2) components were identified as leaking by visual inspection and four (4) were identified as leaking based on the FID readings. All of these components have been appropriately addressed as shown in Attachment II.

We trust that you will find the foregoing satisfactory. Nonetheless, we must advise you that nothing contained herein should be construed as an admission of any facts or liability by, nor as a waiver of any rights or defenses available to, Pfizer.

If you have any doubts or need additional information, please contact me or Mr. Jesús Santos at (787) 774-7492.

Cordially,

Eduardo Cordero
Director/ Team Leader EHS

c. Francisco Claudio - USEPA Caribbean Office
Erwin Smieszek - USEPA Region 2
Gerardo Santiago – JCA

Enclosures

Attachment I

Quarterly Calibration Precision Test and Response Time
TVA-1000B

Date: 03-05-2010
Equipment ID: TVA-1000B S/N 2906365O7
Technician Name: Hector I. Arroyo
Technician Signature: Hector I. Arroyo

$$CP = \frac{A}{B} \times 100$$

where:
CP = Calibration precision percent
A = Average difference between gas concentration and instrument reading
B = Gas concentration

IMPORTANT:
THE *CP* SHALL BE ≤ 10%; THE RESPONSE TIME SHALL BE ≤30 SECS

I. Gas Concentration (*B*): 550 ppmv

	Instrument Reading	Difference	Resp. Tme, sec
Zero Gas	0		
Test 1			3
Zero Gas			
Test 2			3
Zero Gas			
Test 3			3
Average (*A*) :			

CP = _____ x 100 = _____ %

II. Gas Concentration (*B*): 1000 ppmv

	Instrument Reading	Difference	Resp. Tme, sec
Zero Gas			
Test 1			3
Zero Gas			
Test 2			3
Zero Gas			
Test 3			3
Average (*A*) :			

CP = _____ x 100 = _____ %

III. Gas Concentration (*B*): 9500 ppmv

	Instrument Reading	Difference	Resp. Tme, sec
Zero Gas			
Test 1			3
Zero Gas			
Test 2			3
Zero Gas			
Test 3			3
Average (*A*) :			

CP = _____ x 100 = _____ %

LEAK DETECTION AND REPAIR PROGRAM
PFIZER PHARMACEUTICALS,INC.
TVA-1000B CALIBRATION LOG

MODEL: TVA-1000B
ID # :000290636507

		ZERO GAS			SPAN GAS 1			SPAN GAS 2			SPAN GAS 3		
DATE	Tech. ID	Certified Conc. (ppm)	TEI Calibration (ppm)	Exp. Date	Certified Conc. (ppm)	TEI Calibration (ppm)	Exp. Date	Certified Conc. (ppm)	TEI Calibration (ppm)	Exp. Date	Certified Conc. (ppm)	TEI Calibration (ppm)	Exp. Date
03-09-10	HIA	0	0.5	N/A	550	542	06/12	1,000	995	12/12	9,500	9,574	08/12
03-10-10	HIA	0	0.4	N/A	550	558	06/12	1,000	1,006	12/12	9,500	9,403	08/12
03-11-10	HIA	0	0.2	N/A	550	540	06/12	1,000	961	12/12	9,500	9,539	10/12
03-15-10	HIA	0	0	N/A	550	552	06/12	1,000			9,500	9,410	10/12
		0			550			1,000			9,500		
		0			550			1,000			9,500		
		0			550			1,000			9,500		
		0			550			1,000			9,500		
		0			550			1,000			9,500		
		0			550			1,000			9,500		
		0			550			1,000			9,500		
		0			550			1,000			9,500		
		0			550			1,000			9,500		
		0			550			1,000			9,500		
		0			550			1,000			9,500		
		0			550			1,000			9,500		
		0			550			1,000			9,500		
		0			550			1,000			9,500		
		0			550			1,000			9,500		
		0			550			1,000			9,500		
		0			550			1,000			9,500		

Attachment II

Address Work requests Go X

Translations | Items associated | Permits | Documents | Comments | Custom fields | eRecords | Audits

Administration | List view | Record view | Comments | Custom fields

Equipment

Calibration

Work Setup

Work

WO Scheduling

Materials

Repairable Spare

Stocktakes

Procurement

Work order	646785	Reparar visual leak en valvula manual S-86		PPI	--
WO Sub-type	EHS	-- SAFETY - ENVIRONMENTAL WORK OR FINDINGS			
Priority	2	--	WO type	Corrective	
Department	4W214	-- Multi Equip#	Status	Work Requested	
Object	S-86	-- 0 -- TANK		PPI	
Location	L-B108, TANK FARM	-- L-B108, TANK FARM		PPI	
Target date	MAR-05-2010	Project/WBS			--
Problem code	--		Cost code	74-2631	--
			Assigned to	B108	--
Parent work order	--				
Requested by	HARROYO	-- Arroyo, Hector	Entered by	HARROYO	--
Shift	1PPI	-- 1st Shift Barceloneta	Date/time reported	MAR-05-2010 13:0	

PFIZER PHARMACEUTICALS, INC.

FE LEAKER TAG

DATE	03-05-2010	03-10-2010	03-15-2010
TAG NO.	G-HW-04586	—	—
PPM	Visual Leak	30	15
REPAIRED	YES / NO	YES / NO	YES / NO

DO NOT REMOVE

V3 TIGHTENED PACKING VALVE

03-09-2010

Remonitored 03-10-2010

H.I. Arroyo 13:05

Work requests

Address Work requests Go X

Translations | Items associated | Permits | Documents | Comments | Custom fields | eRecords | Audits

Administration | List view | Record view | Comments | Custom fields

Equipment

Calibration

Work Setup

Work

WO Scheduling

Materials

Repairable Spare

Stocktakes

Procurement

Work order	646784	Reparar visual leak en valvula G-XV-02S85-001		PPI	--
WO Sub-type	EHS	-- SAFETY - ENVIRONMENTAL WORK OR FINDINGS		*	
Priority	2	--		WO type	Corrective
Department	4W214	-- Multi Equip#		Status	Work Requested
Object	S-85	-- 0 -- TANK			PPI
Location	L-B108, TANK FARM	-- L-B108, TANK FARM			PPI
Target date	MAR-05-2010		Project/WBS		--
Problem code	--			Cost code	74-2631 --
				Assigned to	B108 --
Parent work order	--				
Requested by	HARROYO	-- Arroyo, Hector		Entered by	HARROYO --
Shift	1PPI	-- 1st Shift Barceloneta		Date/time reported	MAR-05-2010 17:5

PFIZER PHARMACEUTICALS, INC.

FE LEAKER TAG

DATE	03-05-2010	03-10-2010	
TAG NO	G-XV-02585X	—	
PPM	Visual leak	25	
REPAIRED	YES / (NO)	(YES) / NO	YES / NO

DO NOT REMOVE

F2 TIGHTENED FLANGE

03-09-2010

Remonitoreo

H. I. Arroyo 13:00 PM

Work requests

Address Work requests Go

Translations | Items associated | Permits | Documents | Comments | Custom fields | eRecords | Audits

Administration | Equipment | Calibration | Work Setup | Work | WO Scheduling | Materials | Repairable Spare | Stocktakes | Procurement

List view | Record view | Comments | Custom fields

Work order 648783 Reparar leak Fugitive MeCL2 en bomba C-1 1st Bdlg-104 PPI

WO Sub-type EHS -- SAFETY - ENVIRONMENTAL WORK OR FINDINGS

Priority 2 WO type Corrective

Department 4W214 Multi Equip# Status Work Requested

Object C-1 -- 0 -- DISTILLATION COLUMN PPI

Location --

Target date MAR-05-2010 Project/WBS

Problem code Cost code 74-2631

Assigned to B104

Parent work order

Requested by HARROYO -- Arroyo, Hector Entered by HARROYO

Shift 1PPI -- 1st Shift Barceloneta Date/time reported MAR-05-2010 17:41

PFIZER PHARMACEUTICALS, INC.

FE LEAKER TAG

DATE	03-05-2010	03-10-2010	
TAG NO	SR-P-01C01Y	—	
PPM	1,100	42	
REPAIRED	YES / NO	YES / NO	YES / NO

DO NOT REMOVE

F.2 TIGHTENED FLANGE 03-09-2010

Remonitored 03-10-2010

H.I. ARROYO 11:00 AM

Work requests

Address Work requests Go X

Translations | Items associated | Permits | Documents | Comments | Custom fields | eRecords | Audits

Administration | List view | Record view | Comments | Custom fields

Equipment

Calibration

Work Setup

Work

WO Scheduling

Materials

Repairable Spare

Stocktakes

Procurement

Work order	646786	Reparar leak en valvula MeCL2 en Transfer station B-104		PPI	--
WO Sub-type	EHS	-- SAFETY - ENVIRONMENTAL WORK OR FINDINGS			
Priority	2	--		WO type	Corrective
Department	4W099	-- Multi Equip#		Status	Work Requested
Object	BLDG-104	-- 0	-- BUILDING 104 - ORGANIC SYNTESIS PPI		
Location		--			
Target date	MAR-05-2010		Project/WBS		--
Problem code	--			Cost code 74-2631	--
				Assigned to B104	--
Parent work order	--				
Requested by	HARROYO	-- Arroyo, Hector		Entered by	HARROYO --
Shift	1PPI	-- 1st Shift Barceloneta		Date/time reported	MAR-05-2010 18:0

PFIZER PHARMACEUTICALS, INC.

FE LEAKER TAG

DATE	03-05-2010	03-10-2010	
TAG NO.	TS-HV-111B04X	—	
PPM	2,000	60	
REPAIRED	YES / NO	YES / NO	YES / NO

DO NOT REMOVE

F2 TIGHTENED FLANGE 03-09-2010

Remonitored 03-10-2010

H.I. Arroyo. 13:15

Work requests

Address Work requests Go

Translations | Items associated | Permits | Documents | Comments | Custom fields | eRecords | Audits

Administration | Equipment | Calibration | Work Setup | Work | WO Scheduling | Materials | Repairable Spare | Stocktakes | Procurement

List view | Record view | Comments | Custom fields

Work order	646788	Reparar leak en Flange TS-HV-108B04 (Cap 2")		PPI	--
WO Sub-type	EHS	-- SAFETY - ENVIRONMENTAL WORK OR FINDINGS			
Priority	2	--		WO type	Corrective
Department	4W099	-- Multi Equip#		Status	Work Requested
Object	BLDG-104	-- 0	-- BUILDING 104 - ORGANIC SYNTESIS PPI		
Location		--			
Target date	MAR-05-2010		Project/WBS		--
Problem code	--			Cost code	74-2631 --
				Assigned to	B104 --
Parent work order		--			
Requested by	HARROYO	-- Arroyo, Hector		Entered by	HARROYO --
Shift	1PPI	-- 1st Shift Barceloneta		Date/time reported	MAR-05-2010 18:31

PFIZER PHARMACEUTICALS, INC.

FE LEAKER TAG

DATE	03-05-2010	03-09-2010	
TAG NO	TS-HV-108 B04	—	
PPM	600	16	
REPAIRED	YES / (NO)	(YES) / NO	YES / NO

DO NOT REMOVE

Rc Replaced component O ring
Cap. 2" 03-05-2010

Removitorea 03-09-2010

H. I. Arroyo.

Work requests

Address Work requests Go

Translations | Items associated | Permits | Documents | Comments | Custom fields | eRecords | Audits*

Administration | Equipment | Calibration | Work Setup | Work | WO Scheduling | Materials | Repairable Spare | Stocktakes | Procurement

List view Record view Comments Custom fields

Work order 646787 Reparar leak en Flange Bldg-104 1st Floor (Cap 2") PPI

WO Sub-type EHS SAFETY - ENVIRONMENTAL WORK OR FINDINGS

Priority 2 WO type Corrective

Department 4W099 Multi Equip# Status Work Requested

Object BLDG-104 0 BUILDING 104 - ORGANIC SYNTESIS PPI

Location

Target date MAR-05-2010 Project/WBS

Problem code Cost code 74-2631

Assigned to B104

Parent work order Dependent#

Requested by HARROYO Arroyo, Hector Entered by HARROYO

Shift 1PPI 1st Shift Barceloneta Date/time reported MAR-05-2010 18:2

FE LEAKER TAG

PFIZER PHARMACEUTICALS, INC.

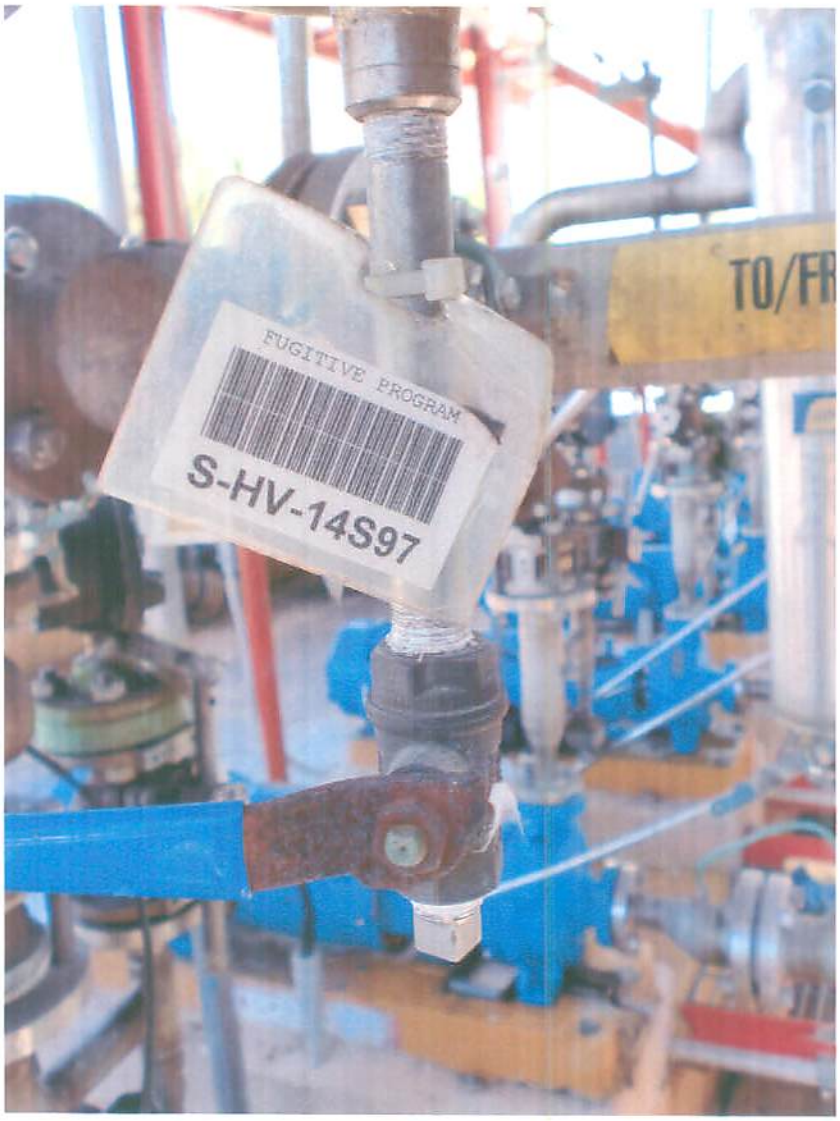
DATE	03-05-2010	03-09-2010	
TAG NO	TS-FL-1004	—	
PPM	510	15	
REPAIRED	YES / (NO)	(YES) / NO	YES / NO

DO NOT REMOVE

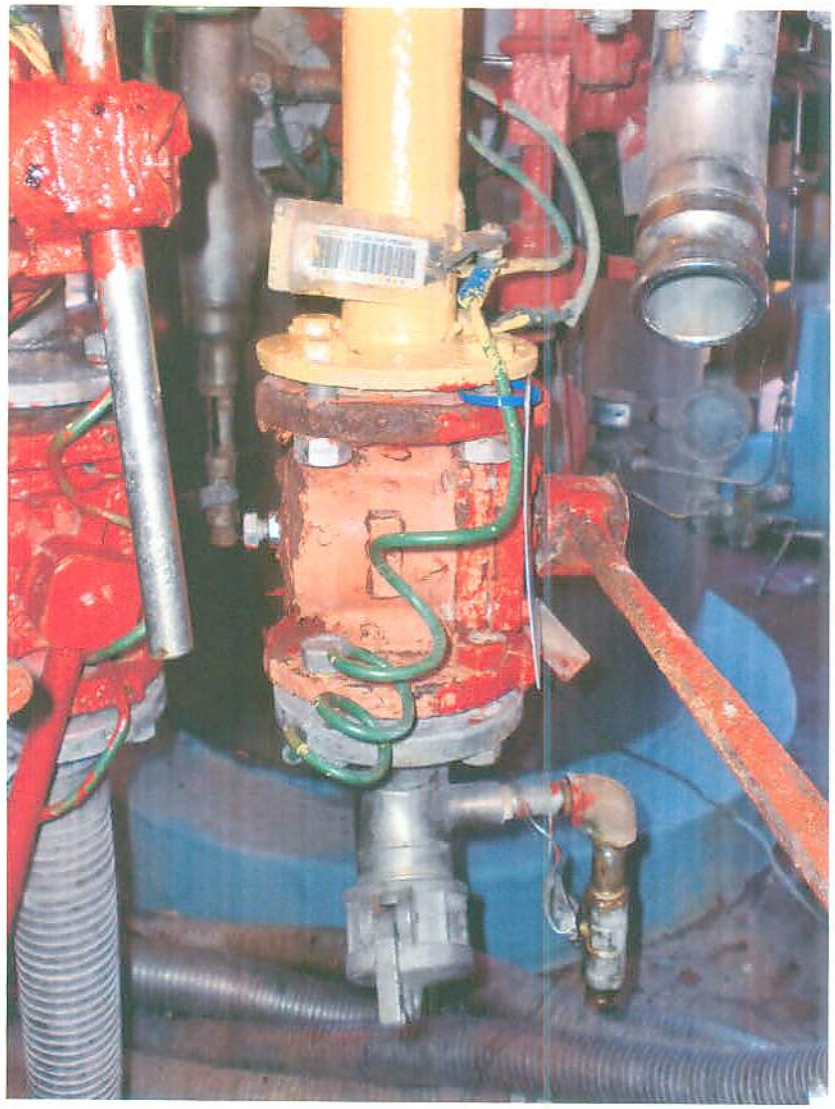
RC Replaced component O Ring
2" Cap. 03-05-2010
Removed 03-09-2010
H. I. Arroyo 13:20

Attachment III

Picture 1. Tag Id. G-FI-012S76 with cap.



Picture 2. Tag Id. S-HV-14S97 cap.



Picture 3. Tag Id. TS-HV-111B04 cap.